New Claims for US National Filing

We claim:

58. A method for the assessment of the number of somatic cells in a liquid milk or milk product analyte material, comprising

arranging a volume of a liquid sample representing the analyte material in a sample compartment having a wall part defining an exposing area, the wall part allowing electromagnetic signals from the sample in the compartment to pass through the wall and to be exposed to the exterior,

exposing, onto an array of active detection elements, a representation of said electromagnetic signals having passed through the wall part from the sample in the sample compartment,

detecting the representation as intensities by individual active detection elements,

processing the intensities in order to identify representations of electromagnetic signals from the somatic cells as distinct from representations of electromagnetic signals from background,

correlating the results of the processing to the number of somatic cells in the liquid analyte material, and

the size of the volume of the liquid sample being so large and the cells therein being identified by one exposure, that the assessment of the number of somatic cells fulfils a predetermined requirement to the statistical quality of the assessment based on substantially one exposure.

59. The method according to claim 58, wherein the representation of the electromagnetic signals is a one-dimensional image representation.

60. The method according to claim ~~1~~ 58, wherein the spatial representation of the electromagnetic signals is a two-dimensional image representation.

61. The method according to claim ~~2 or 3~~ 59, wherein the array of detection elements is arranged in such a way that the a series of detection elements form a straight line.

62. The method according to claim ~~4~~ 61, wherein the array of detection elements is arranged in two directions in such a way that the detection elements form a series of parallel straight lines, the series forming a rectangle.

63.. The method according to claim ~~1~~ 58, wherein the exposure of the spatial representation of electromagnetic signals onto the array of detection elements is performed by focusing an image of electromagnetic signals from at least a part of the exposing area onto the array of detection elements by means of a focusing means.

64. The method according to claim ~~6~~ 63, wherein the focusing means is a lens consisting of one or several elements.

65. The method according to claim ~~1~~ 58, wherein the spatial representation exposed onto the array of detection elements is subject to such a linear enlargement that the ratio of the image of a linear dimension on the array of detection elements to the original linear dimension in the exposing area is between 3:1 and 1:100

66. The method according to claim ~~1~~ 58, wherein the individual somatic cells particles to be assessed are imaged on at the most 5 detection elements.

67. The method according to claim ~~1~~ 58, wherein the interior of the sample compartment has an average thickness of between 20 μm and 200 μm.

68. The method according to claim ~~1~~ 58, wherein sample compartment has dimensions, in a direction parallel to the array of detection elements, in the range between 1 mm by 1 mm and 10 mm by 10 mm.

69. The method according to claim ~~1~~ 58, wherein the volume of the liquid sample from which electromagnetic radiation is exposed onto the array is in the range between 0.04 μl and 4 μl.

70. The method according to claim 58, wherein the sample in the sample compartment is at stand still during the exposure.

71. The method according to claim 58, wherein the sample in the sample compartment is moved through the sample compartment during the exposure, and the exposure is performed over a short period of time to substantially obtain stand still condition during the exposure.

72. The method according to claim 58, wherein at least a major part of the electromagnetic radiation emitted from the sample during exposure originates from or is caused by electromagnetic radiation supplied to the sample from a light source, at least a major part of the radiation from the light source having a direction which is transverse to the wall of the sample compartment.

73. The method according to claim 58, wherein the size of the volume of the liquid sample allows identification therein of at least four somatic cells.

74. The method according to claim 58, wherein the assessment of the number of somatic cells in a liquid milk or milk product analyte material, comprises

arranging a volume of 0.04 µl or more of a liquid sample representing the analyte material in a sample compartment having a wall part defining an exposing area, the wall part allowing electromagnetic signals from the sample in the compartment to pass through the wall and to be exposed to the exterior,

exposing, onto an array of active detection elements, a representation of electromagnetic signals having passed through the wall part from the sample in the sample compartment,

detecting the representation as an intensities by individual active detection elements,

processing the intensities in order to identify representations of electromagnetic signals from somatic cells as distinct from representations of electromagnetic signals from background using an enlargement so that the ratio of the image of a linear dimension on the array of detection elements to the original linear dimension in the exposing area is between 3:1 and 1:100, and such that individual somatic cells are imaged on at the most 25 detection elements of the array of detection elements,

the sample in the sample compartment being at stand still or substantially at stand still during the exposure, and at least a major part of the electromagnetic radiation emitted from the sample during exposure originates from or is caused by electromagnetic radiation supplied to the sample from a light source at least a major part of the radiation from which has a direction which is transverse to the wall of the sample compartment,

and correlating the results of the processing to the number of somatic cells in the liquid analyte material.

75. The method according to claim ~~1~~ 58, wherein the signal which is detected by the detecting elements originates from one or more molecules which bind to, are retained within, or interact with, the biological particles, such molecules being added to the sample or the isolated particles before or during exposure, the molecules being molecules giving rise to one or several of the following phenomena: attenuation of electromagnetic radiation, photoluminescence when illuminated with electromagnetic radiation, scatter of electromagnetic radiation, raman scatter.

76. The method according to claim ~~18~~ 75, wherein an effective amount of one or more nucleic acid dyes and/or one or more potentiometric membrane dyes is added.

77. The method according to claim ~~19~~ 76, wherein a nucleic acid dye or nucleic acid dyes is/are added in an amount of 0.3-30 µg per ml of the sample.

78. The method according to claim ~~19 or 20~~ 76, wherein is/are added one or more nucleic acid dyes selected from the group consisting of: phenanthridines (e.g. ethidium bromide, propidium iodide, acridine dyes (e.g. acridine orange, cyanine dyes (e.g. TOTO™-1 iodide, YO-PRO™-1), indoles and imidazoles (e.g. Hoechst 33258, Hoechst 33342, DAPI, DIPI (4',6-(diimidazolin-2-yl)-2-phenylindole)).

79. The method according to claim ~~1~~ 58, wherein the duration of the exposure is in the range from 100 milliseconds to 5 seconds.

80. The method according to claim ~~22~~ 79, wherein the duration of the exposure is in the range of 0.5 to 3 seconds.

81. The method according to claim ~~22 or 23~~ 79, wherein the exposure is performed as a single exposure.

82. The method according to claim ~~1~~ 58, wherein the sample compartment is part of a disposable unit.

83. The method according to claim ~~1~~ 58, wherein the assessment is performed in an automated system at a rate of at least 300 assessments per hour.

84. The method according to claim ~~1~~ 58, wherein the assessment is performed substantially simultaneously with milking.

85. The method according to claim ~~27~~ 84, wherein the assessment is performed at-line, and preferably in-line with a milking system.

86. The method according to claim ~~27 or 28~~ 84, wherein the sample is a milk sample collected during milking, preferably in such a way that the composition of the sample is a representation of the composition of the entire milk being milked.

87. The method according to claim ~~27, 28 or 29~~ 84, wherein the results of the assessments are transferred to one or several information storage means, the information storage means also being able to store other information about the milking, such as information about milk previously collected from the same animal or herd.

88. The method according to claim ~~30~~ 87, wherein the information storage means includes means to indicate whether the milk being milked should be directed to one or several of storage facilities or outlets, the indication being based on the assessment of the number of somatic cells per volume, well as on other information present in the information storage means about milking of individual animals or bulk tank milk, the other information being selected tron, conductivity, impedance, temperature, fat content, protein content, lactose content, urea content, citric acid content, ketone content, somatic cell count.

89. The method according to claim ~~31~~ 88, wherein the purpose of the direction of any milk being milked to one or several of storage facilities or outlets is to adjust the properties of any bulk of milk with regard to the number of somatic cells per volume by mixing the bulk of milk with milk having a lower somatic cell count, and/or by excluding milk having a somatic cell count exceeding a predetermined limit.

90. The method according to claim ~~1~~ 58, wherein the assessment is carried out after the milking has taken place, the milk not being altered before measurement.

91. A method according to claim ~~1~~ 58, wherein the assessment is carried out after the milking has taken place, the milk being modified before measurement, preferably in such a way that the modification extends the durability of the sample material, the modification being one or several of addition of one or more chemical component which substantially inhibits bacterial growth in the sample material, addition of one or more chemical component which substantially inhibits the growth of fungus, addition of one or more chemical component which has colouring properties said colouring being used to aid visual identification of the milk.

92. A method according to claim ~~1~~ 58, wherein the assessment is carried out simultaneously with the assessment of the amount of any constituent in said sample material, preferably by using the same portion of the sample material for the assessment, the constituent being selected tron, fat, protein, lactose, urea, citric acid, glucose, ketones, carbon dioxide, oxygen, pH, potassium, calcium, sodium.

93. A method according to claim ~~35~~ 92, wherein the assessment of any chemical constituent is based on spectrophotometric measurement, the selected tron; mid-infrared attenuation, near-infrared attenuation, visible attenuation, ultra-violet attenuation, photoluminescence, raman scatter, nuclear magnetic resonance.

94. A method according to claim ~~35 or 36~~ 92, wherein the assessment of any chemical constituent is based on potentiometric measurement, preferably by the use of an ion selective electrode.

95. A method according to claim ~~1~~ 58, wherein the sample material is a milk sample taken from one quarter of the udder, preferably where the purpose of the assessment of somatic cells is to determine the status of health.

96. A method according to claim ~~1~~ 58, wherein the somatic cells or fragments thereof are determined, and the sample material is a milk sample, the sample of the sample material is illuminated in the sample compartment with electromagnetic radiation where at least a portion of said electromagnetic radiation has energy which can give rise to a photoluminescence signal, the signal originating at least from said somatic cells or portions of said somatic cells or components interacting with or bound to the somatic cells or portions thereof.

97. A method according to claim ~~39~~ 96, wherein the signal originates from one or several types of molecules intentionally added to said sample which bind to or interact with the somatic cells or parts of the somatic cells.

98. A method according to claim ~~1~~ 58, wherein somatic cells or fragments thereof are determined, and the sample material is a milk sample, the purpose of the assessment being to obtain information about the health status of a milking animal, the sample of the sample material is placed in a sample compartment by the use of a flow means capable of replacing the sample within the sample compartment with a different sample, the sample of the sample material is illuminated in the sample compartment with electromagnetic radiation where at least a portion of said electromagnetic radiation has energy which can give rise to a photoluminescence signal, the signal originating at least from said somatic cells or portions of said somatic cells or components interacting with or bound to the somatic cells or portions thereof.

99. A method according to claim ~~1~~ 58, wherein somatic cells or fragments thereof are determined, and the sample material is a milk sample, the sample of the sample material is placed in a sample compartment by the use of a flow means capable of replacing the sample within the sample compartment with a different sample the time between the replacement of sample material being shorter than 30 seconds, the sample of the sample material is illuminated in the sample compartment with electromagnetic radiation where at least a portion of said electromagnetic radiation has energy which can give rise to a photoluminescence signal, the signal originating at least from said somatic cells or portions of said somatic cells or components interacting with or bound to the somatic cells or portions thereof.

100. A method according to claim ~~42~~ 99, wherein the signal originates from one or several types of molecules intentionally added to said sample which interact or bind to or interact with the somatic cells or parts of the somatic cells.

101. A method according to claim ~~1~~ 58, wherein somatic cells or fragments thereof are determined, and the sample material is a milk sample, the assessment being performed at the beginning of milking, or during milking, or immediately after milking has taken place, the sample of the sample material is placed in a sample compartment by the use of a flow means capable of replacing the sample within the sample compartment with a different sample flowing milk directly from a milking

unit or flowing milk from an intermediate reservoir which is gradually filled during milking, the sample of the sample material is illuminated in the sample compartment with electromagnetic radiation where at least a portion of said electromagnetic radiation has energy which can give rise to a photoluminescence signal, the signal originating at least from said somatic cells or portions of said somatic cells or components interacting with or bound to the somatic cells or portions thereof.

102. A method according to claim ~~44~~ 101, wherein the signal originates from one or several types of molecules intentionally added to said sample which interact or bind to or interact with the somatic cells or parts of the somatic cells.

103. A method according to claim ~~1~~ 58, wherein somatic cells or fragments thereof are determined, and the sample material is a milk sample, a portion of the sample material is placed in a sample compartment being at least a part of a unit which can be replaced between every assessment or where each of said units can only be used for said assessment of one of said sample materials, the sample of the sample material is illuminated in the sample compartment with electromagnetic radiation where at least a portion of said electromagnetic radiation has energy which can give rise to a photoluminescence signal, the signal originating at least from said somatic cells or portions of said somatic cells or components interacting with or bound to the somatic cells or portions thereof.

104. A method according to claim ~~46~~ 103, wherein the signal originates from one or several types of molecules intentionally added to said sample which interact or bind to or interact with the somatic cells or parts of the somatic cells.

105. A method according to claim ~~1~~ 58, wherein the sample is milk which is undiluted, except for the addition of the reagents used in the assessment, the reagents being non-aqueous.